K040763

APPENDIX A. 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone and Fax Number of Applicant

Resect Medical, Inc.
40874 Calido Place
Fremont, CA 94539, USA
Telephone: (650) 776-4804
Fax: (510) 573-3343

B. Contact Person

Nancy Lincé
Regulatory Affairs Consultant

Telephone: (650) 759-6186
Fax: (510) 885-9935

C. Date Prepared

February 20, 2004

D. Device Name

Trade Name: InLine™ Bi-Polar RF Linear Coagulation Device

Classification Name: Electrosurgical cutting and coagulation device and accessories

E. Device Description

The InLine™ Bi-Polar RF Linear Coagulation Device is a single use, sterile, bipolar, hand-held Radiofrequency (RF) Device that is used to coagulate/ablate tissue. The device is designed for use in intraoperative surgical procedures or used through a non-conductive hand-port during laparoscopic surgical procedures.

F. Intended Use Statement:

The InLine™ Bi-Polar RF Linear Coagulation Device is intended to coagulate tissue during laparoscopic and intraoperative surgical procedures.

G. Substantial Equivalence

The InLine Bi-Polar RF Linear Coagulation Device is substantially equivalent to the Radionics Cool-tip RF Electrode (K984552). It has the same intended use, similar materials of construction, and principles of operation as the predicate device. Both devices are designed to coagulate tissue by delivering RF energy with the use of electrodes.

H. Summary of Data:

Bench testing/functional testing was performed on the InLine™ Bi-Polar RF Linear Coagulation Device to ensure that the product is substantially equivalent to the predicate device and to ensure that the new device does not raise new questions of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2004

Resect Medical, Inc.
c/o Mr. J.A. van Vugt
KEMA Quality B.V.
P.O. Box 5185
6802 Ed Arnhem
Arnhem
Netherlands

Re: K040763
Trade/Device Name: InLine™ Bi-Polar RF Linear Coagulation Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 24, 2004
Received: March 25, 2004

Dear Mr. van Vugt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

K040763

510(k) Number (~~if known~~):

Device Name: InLine™ Bi-Polar RF Linear Coagulation Device

Indications For Use:

The InLine™ Bi-Polar RF Linear Coagulation Device is intended to coagulate tissue during laparoscopic and intraoperative surgical procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040763